Docket No.: 0425-1236PUS1

AMENDMENTS TO THE SPECIFICATION

IN THE SPECIFICATION:

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Please amend the Specification beginning on page 3 line 17 as follows:

Consequently, a method of producing ultrafine drug particles as an emulsion by pulverizing a drug in the solid state under a high pressure using a high-pressure homogenizer (high-pressure emulsifier) has been developed and widely used. This method, however, must essentially include a pretreatment step for allowing a solid drug to have particles sizes at a specific level or below (generally 100 µm or less, preferably 25 µm or less) before introducing the solid drug into the homogenizer. This step serves to prevent clogging of the homogenizer, since, when a solid drug is directly introduced into a homogenizer, the homogenizer may often undergo clogging. Consequently, a special device has been developed in the tradename of Damatorikun, YSDE-1/2-3000 of Yoshida Kikai Co., Ltd. In Japan, and ways and means of, for example, gradually increasing the pressure from a low pressure have been carried out. These techniques, however, are still insufficient to completely remove the risk of clogging of channels of homogenizers. In addition, the pulverization using a high-pressure homogenizer is carried out under a very high pressure to yield required energy, but heating may affect the quality. William et al., for example, disclose a method of producing fine drug particles of less than 400 nm by using a Microfluidizer (Microfluidics Inc.) (US Patent No. 5,510,118). This method requires a step comprising about hundred cycles at a pressure of 15000 to 30000 psi and can be applied only to oil-soluble drugs such as cyclosporin.

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Please amend the Specification on page 8 beginning at line 1 as follows:

The "poor solvent or mixture of poor solvents" in the present invention is not specifically limited, as long as it is a solvent or a mixture of good-poor solvents not substantially dissolving the drug and is a solvent miscible with the drug-containing solution of a good solvent or a mixture of good solvents. For examples, water, acidic waters containing a variety of acids, and basic waters containing a variety of bases may be proposed.

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Please amend the Specification on page 9 beginning at line 9 as follows:

The polyethylene glycol fatty acid esters include polyethylene glycol monolaurate. The sucrose fatty acid esters include sucrose palmitates and sucrose stearie acid. stearates.

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